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Risk and regulatory culture: governing recombinant DNA technology in the UK from 1970–1980

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ABSTRACT

The first discussions relating to the regulation of recombinant DNA technology in the UK occurred in 1970, and were independent of similar discussions happening in the US from 1973. UK regulatory authorities were differently motivated by the range of concerns around risk posed by the new technology. UK authorities implemented a framework that was informed by a specific culture that had roots in scientific and laboratory work practices. The paper reflects on the early close relationships between UK biotechnology industry and university laboratory spaces, and the central concern around laboratory safety and workers rights.

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1. Introduction

The story of the birth of biotechnology and how regulation evolved in the life science industry has been variously told. The history relates to us, the early gene splicing experiments from 1969, the establishment of pioneering firms such as Cetus and Genentech (1971 and 1976) and the first discussions of regulation in 1975 that ended a moratorium in the US, and allowed experimentation to continue.

In Jasanoff's 1993 paper *American Exceptionalism and the Political Acknowledgement of Risk*, Jasanoff writes that 'while the US process for making risk decisions impressed all observers as costly, confrontational ... and unusually open to participation', in Europe 'policy decision about risk remained, as before, the preserve of experienced bureaucrats and their established advisory networks' (63, 66). Rather than adding to ample literature on the US case with a detailed historiography, this work seeks to understand how the rather different regulatory culture in the UK, identified by Jasanoff and others, came to be so distinct in its very early inception. I examine particular events in the UK at a crucial time period from 1970 to 1978 and demonstrate how epistemic communities and the framing of risk underpin the establishment of a fundamentally distinct regulatory culture.

In the UK, the political space from which governance structures evolved, was dominated by the close relationship between government, industry and trade union representatives. This paper makes an original contribution in understanding how, in the era of progressive public administration, this high trust relationship (Hood 1995) was reinforced as incidents in laboratories raised a range of concerns. These concerns were prioritised differently in the US, where the tension between industry and academia has largely become the focus for analysis. Thus whilst recognising a need to implement

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regulation around biotechnology, the UK did not simply follow a lead as set by the US, but rather implemented a framework that was informed by its own specific community and culture that had roots in UK scientific and laboratory work practices. The question this paper will answer is, how was a distinct regulatory culture around biotechnology regulation formed in the UK from 1970 to 1980?

This paper will first set out the analytical concept ‘epistemic community’ and its machinery. Second, the paper describes the events that led to the drafting of the first regulations for genetic manipulation in the US. I draw out two themes evident in this broad history: incidents around health and safety and the relative relationship between stakeholders in the policy making process. The central part of this paper will apply these two themes to the UK context, to frame relevant and detailed descriptions of particular unique events and people. Finally, the paper discusses how the concept of epistemic community may be useful in understanding how a distinct regulatory culture was formed.

2. Epistemic communities

Knorr-Cetina (1999, 1) defines epistemic culture as ‘those amalgams of arrangements and mechanisms bonded through affinity, necessity and historical coincidence – which, in a given field, make up how we know what we know’. Knorr Cetina’s definition of ‘culture’ is rooted in her study of practice in laboratories. It refers to the aggregate patterns and dynamics in the practice of experts.

Experts who share a culture in a given field and are involved in the production of knowledge, have been described by Knorr-Cetina (1981) and later by Haas (1992), as an epistemic community. According to Haas (1992, 3) an epistemic community is ‘a network of professionals with recognised expertise and competence in a particular domain and an authoritative claim to policy-relevant knowledge within that domain or issue-area’. Differently to Lave and Wengers communities of practice concept, Haas uses epistemic community to understand how policy coordination happens in areas with technical and scientific uncertainty (Akrich 2010). The notion of epistemic community has been widely applied to the analysis of regulatory practice in the life sciences (see for example Jansen and Roquas 2005; Kingiri 2011; Meghani and Kuzma 2011). These authors outline how, in the face of relatively high uncertainty and risk, experts are drawn into the policy space as a key part of the policy making machinery.

What interests Knorr Cetina, and what is most important to this paper, is less the production of knowledge, but more the construction of ‘the machineries of knowing’, both social and technical. According to Knorr-Cetina (1999), knowledge construction is shaped by and is inseparable from the machinery used for its production. Epistemic machinery is comprised of those methodologies, techniques, tools and instruments used in our knowledge production and distribution. The machinery, and the culture that surrounds it, is thus located in the micropractices of laboratories (Knorr-Cetina 2007).

What is also relevant to this paper, is how this body of theory might consider shared experiences and significant historical events. It follows that if an event is so significant that it causes change in the micropractices of all laboratories in a given field (e.g. an event that demonstrates considerable risk to health and safety), this in essence, is a demonstrable change to an epistemic culture. The argument is put forward that the emergence of a new regulatory framework in the UK was driven by realities and events and also their perception and interpretation by the epistemic machinery. In other words, how experts at the forefront in dealing with incidents and accidents in the laboratory, were called upon as key experts in an uncertain and emerging regulatory environment.

Of special interest then is Grundmann (1996) critique of Haas’s concept of epistemic community. While Haas posits that the experts making up an epistemic community share common values and believe in the same relationships and tests of truth, Grundmann questions the idea that consensus making is an inherent, non-conflictive characteristic of epistemic communities. For Grundmann, consensual knowledge is not a necessary condition for epistemic communities to exist and work. The

relevance of this critique is in understanding how the events that unfolded concerning safety in biotechnology laboratories might have been variously interpreted and acted on by the policy making community. Grundmann adds that power must not be ignored and the actors most likely to instigate change are those that are able to mobilise resources.

3. The birth of biotechnology and regulatory policy in the United States

Concerns around the safety of laboratory workers framed the earliest of discussion in the US. In 1971, Paul Berg led a team at Stanford University who were working on splicing lambda phage DNA into the DNA of the simian virus SV40. This work was first done by Bergs student Janet Mertz who, while making good progress and optimising the technique, attended a tumour virus workshop at Cold Spring Harbour led by a tumour virologist Robert Pollack (Crotty 2001, 90). Pollack expressed huge concern about the intended work to both Mertz and Berg, describing it as dangerous and outrageous. He perceived risk to laboratory workers if recombinants containing tumour genes from the SV40 found their way into cultures of *E. coli*, the bacterial species most widely used in laboratory research and commonly inhabiting the human intestinal tract (U.S. National Library of Medicine, year not known).

As momentum gathered, these concerns appeared to be echoed through the community of scientists involved. As a result of these concerns Berg and others convened a meeting to assess the risks of working with tumour viruses and recombinant DNA. The meeting held in January 1973 at the Asilomar Conference Center, California, was sponsored by the National Institutes of Health and the National Science Foundation. The meeting concluded with several recommendations to changes in laboratory practice being made, which included periodically monitoring researchers who work with tumour viruses for infection, to prohibit pipetting by mouth, and to use laminar flow hoods during all manipulations involving potentially infectious material (Berg and Mertz 2010). The meeting was attended by around 100 scientists and there was no press coverage.

In 1973 Herbert Boyer, of the University of California at San Francisco, and Stanley Cohen, at Stanford University, were working to advance the work of Paul Berg. Using *ECO RI*, they combined two antibiotic-resistant genes in a plasmid and placed it into *E. Coli*. The announcement of this achievement was made during the 4th day of another conference, The Gordon conference in June of that year, by Herbert Boyer, against the advice of his absent colleague, Stanley Cohen. The work of Cohen and Boyer no doubt placed Berg in an awkward position as he called for a cautious and slow approach. The proceedings, attended by 143 people were quickly thrown into disarray and the remainder of the conference focussed on this announcement and addressing the repercussions. Concerns were voiced at this conference, including the risk of cancer for laboratory personnel handling and scaling up potentially cancer causing viruses, and parallels were drawn with the early years of biological weapons and atomic energy with secrecy surrounding a build-up of nuclear arms (Morgan 2005). A letter to the National Academy of Sciences and the institute of Medicine was drafted, summarising the promises and risks of the new recombinant technology. It also advised that a committee be established to recommend actions and governance for this new science. The letter appeared in the magazine *Science* in September 1973.

Maxine Singer who chaired the Gordon conference, recommended that Berg head that committee. He duly organised a small meeting in April 1974 to discuss what the next steps should be. The committee concluded that scientists across the world should enact a voluntary moratorium on the science, while they deliberated the benefits, risks and governance. They also agreed that as far as possible, decision making should be kept within the professional boundaries of the scientific community (Morgan 2005, 8) and an international meeting should be held (Harron 1983).

The 'Berg letter' written by Berg and 10 others, in July 1974 and published in *Science*, requested that the National Academy of Sciences give attention to rDNA research and its potential biological hazards. They suggested scientists throughout the world place a moratorium on rDNA research and the NIH should establish an advisory committee charged with developing procedures and guidelines for rDNA experiments (Morgan 2005). The NIH did take up a leadership position and in October 1974

established the Recombinant DNA molecule Advisory Committee (RAC) to study the potential bio-hazards presented. And so while concerns grew and became established, the US policy making community started off as a close knit group of university academicians that did not extend beyond those immediately involved in the production of the science.

The issue quickly took on an international dimension and an international meeting that was organised in response to the recommendation by Bergs committee, also in Asilomar (known as Asilomar II), took place in February 1975. It was attended by 90 scientists from the US, 60 scientists from outside the US, 16 reporters and a handful of lawyers. There were no representatives from wider society. Science For The People were a prominent advocacy group in the eye of the public at the time and were not in favour of recombinant DNA experimentation. They drafted a letter to the conference, which was circulated, but not discussed. David Baltimore opened the conference impressing upon the community gathered, the need for scientists to take responsibility and to self-regulate. The groups of lawyers in attendance strongly echoed this position and in addition, advised that other federal agencies be involved, including the Department of Labor, the FDA, the EPA, the Centres for Disease Control and Infection. The lawyers suggested that if the scientific community at the meeting did not arrive at a consensus position and a proposition for a system of self-regulation, federal agencies would take the lead in regulating the new science. Not only this, but publics would likely become involved and this would lead to restrictions in scientific experimentation. The dissenting voices of scientists, those that attempted to express concern about the possible social uses of genetic engineering, were effectively silenced, and the issues were reduced to a technical question of containment (Wright 1998).

A draft statement was circulated on the last morning of the conference, written by the organising committee on the previous night. Conference attendees voted on various pieces of the statement. It was finally agreed that the moratorium should be lifted and work should proceed, with safeguards and with some exceptions. The provisional statement was released at a press conference on the February 28 1975. It was immediately adopted by the NIH Recombinant DNA Molecule Program Advisory Committee (John Hopkins University 2018).

In May of 1975 the RAC met to frame the guidelines for rDNA research and July, an RAC subcommittee was held to draft the provisional guidelines. The NIH advisory committee invited public comments in November 1975 and then published its own guidelines. Many doubts and fears from the public and from scientists were expressed to the committee during the consultation period.

Wright (1998) describes the regulatory arena up until the end of 1975, as one that was largely controlled by, and responsive to scientific elites. Wright (1994) suggests that US public participation before 1976 was largely an illusion, but in 1976 there was a change in direction, or a 'second phase' in policy making as public concern and controversy erupted (Wright 1998).

The Congress did not play a major role in the early development of rDNA guidelines. The House of Representatives committee on Science and Technology, and specifically, its subcommittee on Science, Research and Technology, kept pace with the issue by preparing a series of reports. Following the Asilomar conference, in April 1975 (and again in September 1976), the senate committee on Labour and Public Welfare, specifically the Subcommittee on Health, held hearings on rDNA technology. It was not until 1977 however that the Congress decided to take direct action and introduced 16 bills to regulate recombinant DNA research. The bills called for the development of bacteria and plasmids that could be prevented from escaping from the laboratory environment. None of the bills passed however.

It is argued that the regulatory culture in the US was shaped by the wider political context in which these discussions were taking place. Krinsky (2005) for example discusses a number of relevant factors including the birth of the environmental movement in the 60s and the rise of political activism in the 1970s that the US government saw fit to respond to. The 1960s sunshine laws and 1970s Freedom of Information Act in the US required meetings of agency officials to be open to press and public. The Environmental Protection Agency was created in 1970, and the Office of Technology Assessment in 1972. Technology assessment and environmental impact was introduced into Federal programmes and a new sensibility toward government ethics followed the post Watergate

era. Importantly there were revelations about unethical human experiments involving radiation, psychotropic drugs and biological agents (e.g. the Tuskergee Syphilis study). A new generation of biologists completed their studies during the peak of the Vietnam War and the signing of the biological weapons convention (1972) having studied under the guidance of professors who spoke about the role of physics in the nuclear arms race (Krimsky 2005). Krimsky (2005) suggests that over the course of Asilomar I and II, discussion of risk turned from informed consent of the lab worker to informed consent of the community.

The development of private interests in the late 1970s further acted to frame risk and shape policy. Scientists in the US, attracted by the potential for profit and intellectual freedom, were the first to spin out of their universities, establishing companies like Genentech in 1976. From the first demonstration of bacterial expression of somatostatin gene in 1977, multinational and venture capital firms began to invest in these small genetic engineering firms. Once it became clear that congressional interest could be blocked, the scientific community with the support of industry began to push for a reversal in policy. And this happened from 1979 onward as the practice of ‘containment of unknown hazard’ was gradually replaced in policy by the claim that genetic engineering posed ‘no extraordinary hazard’ (Wright 1998).

The US case highlights two themes that can be applied to the UK. Firstly the nature of the policy making elite in this narrow field and its relationship to other policy groups, industrial partners and the wider political context. These relationships in turn impact the way that risk is framed, which is the second theme discussed in the UK case below.

4. Biotechnology and regulatory policy in the UK

4.1 Initial framings of risk

In the early 1970s, a group of European ‘forerunner’ countries quickly opted for a voluntary approach based on NIH guidelines. There were differences between European neighbours however. Some left the solution to technical experts and others opted for a more inclusive approach, soliciting view from other sectors of society. Torgeson (2002) specifically note two things of particular relevance in the UK. Firstly there was very little significant wider public concern or debate at this time, even less than occurred in the US. British policy was focused on occupational hazards and the debate around the ‘epidemic pathogen’ that happened in the US, was not seen as relevant (Wright 1998). Secondly, the initial guidelines adopted in the UK, preceded those produced by the NIH. The remainder of this paper is dedicated to understanding how guidelines in the UK were established given that Britain did not use as a basis, the guidelines produced by the NIH.

The literature charting governance of UK biotech often takes as its starting point the work of the Ashby committee and its report published in 1974 (see Gottweiss 1998). While regulatory policy and policy makers in the UK no doubt closely followed proceedings in the US, I argue that the various committees and working groups central to policy making were drawn from an epistemic community that by that time, had already established a risk framing perspective that had more to do with accidents and incidents in UK laboratories.

A committee on health and safety at work was appointed in May 1970 by Barbara Castle then secretary of state for employment and productivity for the Labour government. The committee was chaired by Lord Alfred Robens, a trade unionist and Labour politician. The committee reported in June 1972. The Robens report opens with the statement ‘Every year something like 1,000 people are killed at their work in this country. Every year about half a million suffer injuries in varying degrees of severity’ (Robens and Robens 1972, 1). It controversially concluded that ‘apathy’ by employers and employees was primarily to blame. Furthermore, excessive or overly detailed regulation could promote apathy and a more effective self-regulating system was needed with the burden falling on employers and workers.

Despite the long term trend in the improvement of working conditions and the general fall in fatalities due to improved medical care etc., the report suggests a radical rethink of the system as a whole because of toxic and dangerous new chemical substances. The report discusses particular cases including asbestos (and the link to cancer) and though its link to health and safety at work is not made clear, also the case of thalidomide.

Chapter 14 of the report specifically addresses safety in research institutes and universities. The report sought to expand health and safety legislation from conventionally ‘dangerous’ industries such as coal mining, to include all workplaces. Listed in the appendix of the aforementioned report, amongst those that submitted evidence for the report are various unions and lecturers in charge of university-affiliated occupational hygiene laboratories. Analysis of the Robens Committee’s work by Sirrs (2015), finds an emphasis on consensus and ‘tripartism’ (the involvement of government, industry and trade union representatives). Though there was much criticism at the time of Robens faith in voluntary-effort and self-regulation the Trade Union Congress and the Confederation of British Industry still felt it represented an advance over the existing system. Sirrs argues that the principles established by the Robens report (those of self-regulation and onus on the individual worker and employer to mitigate risk) continued to underpin regulatory frameworks as they evolved in the UK.

4.2 Incidents and outbreaks; the concerns of unions

In March 1973, a graduate laboratory technician employed at the London School of Hygiene and Tropical Medicine was admitted to St. Mary’s Hospital, suffering from suspected meningitis or glandular fever. She was admitted to an open ward where she came into contact not only with other patients, but with two visitors who tragically died. The technician had contracted Smallpox and had passed it on in the ward setting (Marsden 1974).

Sir Keith Joseph, the Conservative Secretary of State for Health, appointed the Cox committee to hold an inquiry into the origin of the smallpox outbreak. The preliminary meeting took place in May 1973 and the report from this working party was published in 1974 under the Labour Government Secretary of State for Health, Barbara Castle. The report specifically recommended: 1. The establishment of a permanent committee of experts (i) to designate a list of pathogens, laboratory work with which constitutes a major threat to public health; (ii) to maintain a register of departments where work with designated pathogens is being undertaken; (iii) to formulate and regularly review a code of practice necessary for the safe conduct of all such procedures; and (iv) to have power to ensure that the code is followed (Marsden 1974). A code of practice was implemented: the Code of Practice for the Prevention of Infection in Clinical Laboratories and Post-mortem Rooms (commonly known as the ‘Howie Code, after its chairman James Howie) was developed (Cottam 1994).

Meanwhile, The Health and Safety at Work Act 1974 (UK Gov 1974) came into force. It implemented many of the recommendations advanced by the Robens report. The HSWA was described as ‘a bold and far-reaching piece of legislation’ by HSE’s first Director General, John Locke. Where earlier regulations applied only to factories, the HSWA applied to universities too. The Act established the Health and Safety Commission (HSC) for the purpose of proposing new regulations, providing information and advice and conducting research. HSC’s operating arm, the Health and Safety Executive (HSE) was formed shortly after in order to enforce health and safety law. The HSC in its first few months was concerned with asbestos, construction, dusts, ionising radiation, lead, noise, vinyl chloride and importantly, genetic manipulation. The scientific community in the UK, in 1974 would have been aware of the discourse around genetic manipulation and safety concerns at the international level, though there is a lack of evidence that can be drawn upon to substantiate this claim. Union membership was on the rise and academic unions were concerned, perhaps due to the laboratory incidents that are described below.

While the Cox committee was set up to investigate the 1973 incident, the government set up another committee in 1975 under the chairmanship of Sir George Godber to examine wider

questions of how dangerous pathogens should be regulated. The Godber Committee recommended that a permanent expert committee, the Dangerous Pathogens Advisory Group (DPAG), be set up under the health and safety Executive, to advise the government on safety measures and to investigate the suitability of specific laboratories for handling particular pathogens (McGinty 1979). It was proposed the group would report to the department of Health and Social Services and be granted statutory power under the health and safety at work act (Leggett and Sleight 2017).

In August 1978, there was another outbreak of smallpox, this time at the University of Birmingham which caused the death of a medical photographer who worked there. Before the conclusion of the investigation into how the virus was transmitted was reported to the DHSS (Anonymous 1978a) there were a number of other controversies. These included criticism from the trade unions over safety standards at the university. Also the question of why the laboratory was given approval to work with small pox by the Dangerous Pathogens Advisory Group in 1976, despite refusal from the WHO to allow these activities after December of that year. The conclusions of the report (by R. Shooter a member of the board of the public health laboratory service), were well publicised and the report was published in July 1980. The Shooter team recognised the legitimate international dimension of the concern, and took steps to demonstrate this. The WHO sent an observer to participate in the first three meetings of the investigation, and this placed the WHO on a par with the DHSS and the Trades Union Congress, as legitimate bodies weighing in on the issue (Sims 1988). The report highlighted the numerous failings within the laboratory itself in not complying with the voluntary standards as laid down by DPAG (Anonymous 1978b).

4.3 Regulation on genetic manipulation; the closed and narrow nature of UK policy circles

As news began filtering through from the US on Asilomar II, a second line of regulatory authority began to develop in the UK in parallel with the HSE and DPAG. The Advisory Board for the research councils (the University Grants Committee, under the jurisdiction of the Department of Education and Science) set up a working party of senior scientists under Lord Ashby, a botanist who held positions at Cambridge University and on the Royal Commission on Environmental Pollution just prior to this work. The board was to make an assessment of the potential benefits and potential hazards of techniques which allow the experimental manipulation of the genetic composition of micro-organisms. The report of the working party was published in January 1975. It stated that members were ‘convinced that the hazards are less serious than some of us had first thought’ and that work should go ahead provided precautions are taken. The Ashby report recommended that safety controls be voluntary (Gibson 1986).

Following Ashby, another working party set up in August 1975 by the Department of Education and Science, chaired by professor Robert Williams (bacteriologist and director of the public health laboratory service), was tasked with preparing a code of practice for work involving genetic manipulation (Gibson 1986). In August 1976, the party published its recommendations (Lewin 1976). Its document stated that ‘no genetic manipulation experiment should be undertaken in containment conditions less stringent than those used for work with common pathogens’. It was this committee that specified a tiered categorisation of four containment levels for different types of genetic manipulation (Leggett and Sleight 2017). The Williams Report did not attempt to be absolutely specific about the acceptability of experiments, suggesting each proposal be assessed individually with categorisations and regulation becoming more specific with time and experience. This ‘case law’ approach was very different to the system of approval as was emerging in the US and was favoured by the European Science foundation because of its flexibility.

The Williams report was published after three months, the same day as the above mentioned report produced by the HSC. The two documents were very much opposed. Not only did the HSC attempt to draw up a specific description of genetic manipulation, it decided to include the traditional tool of genetics, which had already been in use for many years without hazard. An article in the New Scientist in October 1976 reported:

With the Ashby and Williams report behind them researchers would have been all set to gear up for the undoubtedly fruitful research that lies ahead. But the HSC's consultative document has put a stop to that, and unmistakable gloom, anger and fear has settled over the country's genetic manipulators. With the Williams report the researchers could feel a road sympathy; by comparison the HSC's document is an alien being ... its contents appear to take the whole genetic engineering debate right back to square one ... Worse, it appears to have been written by someone having no idea of what genetic engineering is about. (Lewin 1976, 220)

Despite the contestation over regulatory space, the Genetic Manipulation Advisory Group (GMAG) was set up, from the recommendations of the Williams report and met for the first time in December 1976. GMAG should be, according to the Williams report, an independent advisory body, granted powers under the Health and Safety at work act which would require laboratories to submit their proposals to the group (Lewin 1977). GMAG would then advise researchers on the categorisation of the work and on the relevant code of practice. The details of experiments should also, according to the Williams report, be submitted to the Health and Safety Commission which would, in turn, receive technical advice from GMAG (Cripps 1981). An entirely closed shop was not intended and GMAG aimed to be broadly representative. It therefore included eight scientific and medical experts, four members representing public interests, four members of the TUC, two representatives of the CBI, and one member representing university vice chancellors and Principals (Beardsley 1984). As described below, it was however strongly influenced by the way decision making was undertaken by its director.

Until July 1978, when GMAG achieved full legal status, its members were bound by the Official Secrets Act. After this date, its members were covered by section 28 of the Health and Safety and Work Act (1974), a provision that allows disclosure of the committees business if health is at risk (Lewin 1977).

Throughout the 70's GMAG managed to retain a narrow focus on technical issues and laboratory safety. The chairman of the House of Commons select committee on Science and technology, Arthur Palmer stated 'it is very surprising that the Genetic Manipulation Advisory Group (GMAG) has not been asked to consider the wider aspects of this important new science'. To which the acting head of the GMAG delegation, Professor Mark Richmond responded 'early in our meetings we agreed we would not address either the scientific merit of research proposals or the social ramifications of the science'. The new scientist reports that 'MPs were visibly shaken at Richmonds remarks' (Anonymous 1978a, 915).

In 1978, initiated by Sydney Brenner and developed by various subcommittees, GMAG proposed a new Risk Assessment Scheme, which they hoped would be adopted by Europe in preference to NIH controls. While unions in the UK remained committed to GMAG controls (Dickson 1978), the scheme was rejected by private industry (the CBI pressing for parity with NIH), the EMBO and received only a cool response from other European countries. Wright (1994) suggests that the European response coloured its reception in the UK. Scientists feared that complying with GMAG would mean overzealous safety committees, unnecessary delays and costs (Wright 1994).

GMAG was coming under pressure to relax controls in line with the US. William Henderson became the new chair of GMAG in January 1979. He promised scientists fewer delays and faced down the unions, refusing to allow the union time to consult with their constituents. This was quite different to the previous chairman, Gordon Wolstenholme who tended to wait for the unions to consult (Wright 1994). Controls were somewhat relaxed, and by March 1979 the risk assessment scheme included criteria for categorisation that was very close to NIH guidelines.

The Royal Society and the Committee on Genetic Experimentation (COGENE), in April 1979, jointly sponsored an international conference on recombinant DNA, held at Wye College, Kent. Various notable characters and characters from the American story were in attendance including Maxine Singer, Stanley Cohen and James Watson. The April COGENE Royal Society meeting left no doubt that the Americans intended to dismantle their controls over recombinant DNA technology, with support of the NIH (Wright 1996). The continued closed nature of policy making in the UK on the other hand, was a talking point. Professor Robert Hugh Pritchard spoke about scientist perceptions of regulatory policy making:

While I have been impressed by the evidence of such a dialogue in the United States, there has been no such dialogue in Britain. There is no mechanism for such a dialogue. I do not know how GMAG reaches its decision because they are arrived at with all the openness of a papal enclave. (Pritchard, 1979, cited by Morgan and Whelan 2013, 226)

Europe ultimately diverged from the direction set by the US, pursuing a process rather product based evaluation of GMOs (Dunlop 2000). GMAG was replaced by the Advisory Committee on Genetic Manipulation (ACGM) in 1984, a committee that reported to the HSE, that had employers and employee representatives, but no public interest groups (Beardsley 1984). The unions were however, an important group which briefly, but strongly influenced the direction of GMAG up until 1978.

The general trend internationally towards the end of the 1970s was to follow the NIH model. 1979 saw the conservative government gaining power, a trend towards deregulation and the prioritisation of biotechnology as a promising new industry. Regulatory control over genetic manipulation was now seen as more stringent in the UK to the point at which it might be thought of as detrimental to economic growth and prosperity. GMAG was gradually dismantled and the last of its functions were transferred to the health and safety executive in 1984 (Wright 1994).

The end of the 1970s saw the establishment of the biotechnology industry in the UK. Leading molecular geneticists situated in Europe at this time largely operated out of university laboratories, they continued to be an intrinsic part of the academic community. Their spaces were carefully regulated and monitored by the mechanisms of oversight that came into being as a result of the small pox outbreaks in 1973 and 1978. They quietly went about their experiments, rarely gaining admittance past the closed doors that marked off the various committees in charge of writing regulation and policy. This is perhaps in contrast to molecular biologists and private interests in the US.

5. Conclusion: epistemic cultures and resistance to change

The story of regulation in US and the UK show a number of similarities. In both cases in the initial stages, policy making amidst uncertainty drew upon the expertise of the practitioners at the forefront of the science. Policy making occurred in a relatively closed group, with decisions being made without wide consultation and experts changing practice at the laboratory level in response to perceived concerns.

In the UK however, a very early framing of risk that tended more towards individualism was instigated by the Robens report. Mitigating apathy would be done through a system of self-regulation which would see the burden of risk management falling on employers and workers. In this initial framing of risk, wider society and its concerns were shut out of the debate, a theme which is shown to recur for example with GMAG later managing to retain a narrow focus on technical issues and laboratory safety.

In the US, discussions around the epidemic pathogen were foregrounded and the epistemic machinery – the methods, tools and techniques, changed in anticipation of this general risk to the public. In the UK however, the experts drawn into policy making had already been impacted by the smallpox incident of 1973 and the resulting code of practice that was widely implemented in 1974. The micropractices of laboratories changed in response to a proven risk of a different nature – a risk that singularly affected laboratory staff.

With risks framed and experienced in this way in the UK, the involvement of the trade unions as worker representatives was inevitable. The unions were central to the debate until the change of government in 1979 and under Wolstenholme's GMAG chairmanship. This in addition to the closed nature of debate and consultation is likely responsible for the continued narrow framing of risk and the focus on the safety of laboratory workers.

There was contestation over regulatory space with the HSE and the Williams report offering ways forward. As Grundmann (1996) observes, the epistemic community continued to exist and work despite the conflict. The configuration of the regulatory space, shaped by the strong influences of

experts and their experiences, continued to resist change until the much stronger forces of deregulation and the prioritisation of biotechnology as a promising new industry in an international landscape.

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